REMARKS/ARGUMENTS

Claims 1-19 were originally filed. By this paper, claims 1, 3, 6, 14 and 17 are amended and claim 11 is cancelled. Accordingly, claims 1-10 and 12-19 remain for reconsideration.

Claim Rejections - 35 USC § 112

Claims 3, 6, 11 and 17-19 were rejected by the Examiner under 35 USC § 112, second paragraph, as being indefinite. The claims have been amended to cure the informalities noted by the Examiner. Namely, the word "**from**" has been substituted for the term "**for**" in claim 3; the extraneous "**for**" has been deleted from claim 6; the dependency of claim 17 has been changed to clarify that the recited liposome is not a eukaryotic vector; claim 11 has been canceled; and claim 14 has been amended to delete the extraneous recited step of inserting the HA1 encoding sequence into the vector.

Claim Rejections - 35 USC § 102

Claims 1-2, 6-7, 9-10 and 13 stand rejected under 35 USC. §102(b) as being anticipated by either Olsen et al. (*Vaccine* 1997 Jul;15(10):1149-56); Larson et al. (*J Virol.* 1998 FEB;72(2):1704-8); and/or Lunn et al., (*Vaccine.* 1999 May 4; 17(18):2245-58). The Examiner identifies Olsen as teaching nucleic acid vaccines for equine influenza virus utilizing the full length HA gene from the equine-2 influenza strain A/Equine/Kentucky/1/81. Larson is said to teach the coadministration of Olsen's vaccine with an adjuvant. Lunn is said to teach methods of inducing an immune response utilizing the Olsen vaccine. In light of the amendments made herein, the rejections are respectfully traversed.

The Examiner notes that the gene used by Olsen was the full-length HA gene, but points out that the claims as originally filed utilized the open-ended transition term "comprising" in identifying the claimed DNA. Claim 1 has been amended by substituting the more restrictive transition phrase "consisting essentially of" for the term "comprising" in claiming the isolated DNA encoding the HA1 sequence. Thus, the claims now distinguish over the full-length HA gene which is the subject of the cited references.

The specification addresses the advantages that flow from Applicant's discovery that a DNA vaccine containing the encoding sequence for the HA1 segment of the HA glycoprotein confers protective immunity. Applicant discovered that the expression of the HA1 segment alone is sufficient to illicit protective immunity and discovered that a much lower dosage of the HA1 vaccine is required to confer protection when compared to a DNA vaccine expressing the full length HA gene (see Specification, paragraphs 0017 and 0053). In addition, the claimed vaccine possesses advantages over current vaccines insofar as updating of the vaccine requires only the replacement of the antigen by inserting the HA1 in encoding sequence from a new virus. The vaccine can also be engineered to optimize the immunogenicity of the expressed antigen (see Specification, paragraph 0018).

Considering the amendments to the claims and the noted advantages of the claimed invention over the cited references, reconsideration of the rejections under Section 102 is respectfully requested.

Claim Rejections - 35 USC § 103

Claims 3-4, 5, 8, 12, 14-15, 16 and 17-19 stand rejected under 35 U.S.C. §103(a) as being unpatentable over combinations of Olsen and/or Lunn with various secondary references.

As noted above, the pending claims have been amended to distinguish Applicant's claimed DNA vaccines and methods utilizing the HA1 encoding sequence of the HA gene verses Olsen and Lunn, which are directed to vaccines and methods utilizing the full-length HA gene. Further to the comments made above with respect to the primary references, it is again noted that the immunogenicity of the claimed DNA vaccine is significantly enhanced over those of the prior art. This is because in the absence of HA2, synthesized HA1 will not be membrane bounded, and hence more HA1 molecules are allowed to be released and taken up by antigen presenting cells to elicit a stronger immune response. Still further, utilizing the present invention protective immunity was elicited by as low as 0.01 μg DNA per gram of body weight, which is 10-fold less than that reported by Wong et al. (*Vaccine*. 2001 Mar 21;19(17-10):2461-7), one of the secondary references cited by the Examiner, and is 2-fold less than used by gene gun inoculation (see Specification, paragraph 0053). These surprising findings support the patentability of the instantly claimed invention.

Considering again the amendments to the claims and the noted advantages and benefits of the claimed invention over the cited references, reconsideration of the Section 103 rejections is respectfully requested.

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This paper is intended to constitute a complete response to the outstanding Office Action. Please contact the undersigned if it appears that a portion of this response is missing or if there remain any additional matters to resolve. If the Examiner feels that processing of the application can be expedited in any respect by a personal conference, please consider this an invitation to contact the undersigned by phone.

Respectfully submitted,

9/8/05
DATE

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